K110787

APR 2 1 2011

Orthogem

Submitter	Orthogem Ltd Biocity Pennyfoot Street Nottingham NG1 1GF UK
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Contact Person	Dr Wei-Jen Lo
Date prepared	14 March 2011
Trade Name	TriPore® TDD
Common Name	Synthetic, porous calcium phosphate bone graft
Classification	Resorbable calcium salt bone void filler devices have been classified by the Orthopedics Device Panel as Class II Special Control per 21 CFR 888.3045. Product code: MQV
Predicate Devices	(1)TriPore Calcium Phosphate granules K070132 (2) FibriJet® Graft Delivery Device K100754
Device Description	TriPore TDD is an open bore syringe prefilled with TriPore synthetic bone graft granules in three different compositions: (1) 100% pure hydroxylapatite; (2) biphasic mixture of 90% hydroxlyapatite and 10% tri-calcium phosphate; (3) biphasic mixture of 15% hydroxlyapatite and 85% tri-calcium phosphate TriPore TDD comes in two sizes – containing 5cc and 10cc of TriPore granules.
Intended Use	TriPore TDD_{HA}, TDD_{BP90}, and TDD_{BP15} is intended to be packed into bone defects of the skeletal system (extremities, posterolateral spine or pelvis) which are not intrinsic to the stability of the bony structure. These defects may be surgically created voids or from traumatic injury to the bone. The device gradually resorbs and is replaced with bone during the healing process. Rigid fixation techniques should be used in conjunction with this device.
Technological Characteristics compared to the predicate devices	(1) Predicate device TriPore K070132: TriPore TDD contains exactly the same TriPore (HA or BP90 or BP15) as the predicate device. (2) Predicate device FibriJet Graft Delivery Device K100754: TriPore TDD contains exactly the same open bore syringe as the predicate device.
Determination of substantial equivalence (non-clinical data)	Orthogem has determined that TriPore TDD is substantially equivalent to the predicate devices on the basis that the synthetic bone graft granules in TDD are exactly those in the predicate device.
Determination of substantial equivalence (animal data)	Extensive animal studies on TriPore, and recorded in k070132 apply to TriPore TDD and have not been repeated. Animal data is not applicable to the TDD syringe.
Conclusions	Orthogem concludes that the non-clinical tests carried out on TriPore TDD demonstrate that it is safe. Effective and function as well as the predicate devices.
Other information deemed necessary by the FDA	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Orthogem Ltd
% Dr. Wei Jen Lo
Biocity, Pennyfoot Street
Nottingham NG1 1GF
United Kingdom

Re: K110787
Trade/Device Name: TriPore TDD
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: March 14, 2011
Received: March 25, 2011

Dear Dr. Lo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

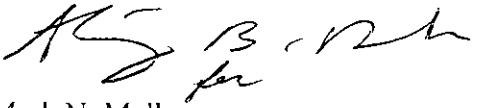
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K110787

Device Name: TriPore TDD

Indications For Use:

TriPore TDD_{HA}, TDD_{BP90}, and TDD_{BP15} is intended to be packed into bone defects of the skeletal system (extremities, posterolateral spine or pelvis) which are not intrinsic to the stability of the bony structure. These defects may be surgically created voids or from traumatic injury to the bone. The device gradually resorbs and is replaced with bone during the healing process. Rigid fixation techniques should be used in conjunction with this device.

Prescription Use: YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110787